510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K031497

B. Analyte:
3,4 methylenedioxymethamphetamine, secobarbital, oxazepam, methadone, nortriptyline

C. Type of Test:
qualitative

D. Applicant:
Amedica Biotech, Inc.

E. Proprietary and Established Names:
Amedica Drug Screen MDMA-BAR-BZO-MTD-TCA

F. Regulatory Information:

1. Regulation section:
   21 CFR862.3610; 21 CFR862.3150; 21 CFR862.3170; 21 CFR862.3620; 21 CFR862.3910
2. Classification:
   Class II
3. Product Code:
   DJC; DIS; JXM; DJR; MLK
4. Panel:
   Clinical Toxicology Panel (91)

G. Intended Use:

1. Intended use(s):
   See Indications for use.

2. Indication(s) for use:
   The Amedica Drug Screen MDMA-BAR-BZO-MTD-TCA Test is an immunochromatographic assay for the rapid detection of 3,4 methylenedioxymethamphetamine, secobarbital, oxazepam, methadone and nortriptyline in human urine at the following cutoff concentration

3,4 methylenedioxymethamphetamine	500 ng/ml
secobarbital	300 ng/ml
oxazepam	300 ng/ml
methadone	300 ng/ml
nortriptyline	1000 ng/ml

   This test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter use.

3. Special condition for use statement(s):
   Not intended for point of care sites. This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be

used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test results, particularly when preliminary results indicated positive.

4. Special instrument Requirements:
   Not applicable. The device is a visually read single-use device.

H. Device Description:

For the Test Strip: the product is a single-use dipstick device. Operators dip the test strip into the urine and the reaction is initiated by movement of the sample through the test strip.

For the Test Card: the product is a single-use device in a cassette format. Operators add several drops of the sample to the sample well. The test reaction is initiated by movement of the sample through the test strip.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Instant-View MDMA Test, Alfa Scientific Design, Inc.
   Instant-View Barbiturate Test, Alfa Scientific Design, Inc.
   Instant-View Benzodiazepine Test, Alfa Scientific Design, Inc.
   Instant-View Methadone Test, Alfa Scientific Design, Inc.
   Instant-View TCA Test, Alfa Scientific Design, Inc.

2. Predicate K number(s):
   K022501; K010125; K003879; K010014; K022693

3. Comparison with predicate:
   Both devices are for the qualitative determination of the same analytes in the same matrix, and utilize the same cutoff concentration. Both are visually-read single use devices.

J. Standard/Guidance Document Referenced (if applicable):

The sponsor did not reference any standard/guidance in this submission.

K. Test Principle:

The test employs lateral flow immunochromatographic technology.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
      The product has been evaluated (1) random error of visual interpretation by three different observers interpreting duplicate tests on a single sample source 2 times a day for 20 days, and (2) random error of multiple observers interpreting a single test. Five urine

specimens near cutoff concentration were prepared by spiking GC/MS confirmed standard solution into filtered drug free urine. Test results are as follows:

MDMA con. ng /ml	No. of Samples	1 -	1 +	2 -	2 +	3 -	3 +
250	120	120	0	120	0	120	0
375	120	120	0	120	0	120	0
5uu	120	b4	66	54	66	54	66
625	120	25	95	25	95	24	96
750	120	0	120	0	120	0	120

BAR conc. ng /ml	No. of Samples	1 -	1 +	2 -	2 +	3 -	3 +
150	120	120	0	120	0	120	0
225	120	120	0	120	0	120	0
300	120	63	57	63	57	63	57
375	120	30	90	30	90	31	89
450	120	0	120	0	120	0	120

BZO conc. ng /ml	No. of Samples	1 -	1 +	2 -	2 +	3 -	3 +
150	120	120	0	120	0	120	0
225	120	120	0	120	0	120	0
300	120	56	64	54	66	54	66
375	120	35	85	33	87	35	85
450	120	0	120	0	120	0	120

MTD conc, ng /ml	No of Samples	1 -	1 +	2 -	2 +	3 -	3 +
150	120	120	0	120	0	120	0
225	120	120	0	120	0	120	0
300	120	54	66	52	68	52	68
375	120	37	83	36	84	36	84
450	120	0	120	0	120	0	120

TCA Conc ng /ml	No of Samples	1 -	1 +	2 -	2 +	3 -	3 +
500	120	120	0	120	0	120	0
750	120	120	0	130	0	120	0
1000	120	59	61	58	62	57	63
1250	120	38	82	37	83	37	83
1500	120	0	120	0	120	0	120

b. Linearity/assay reportable range:
Not applicable. The assay is intended for qualitative use.

c. Traceability (controls, calibrators, or method):
The device has an internal control. Users are instructed to follow federal, state, and local guidelines concerning the running of external quality controls.

d. *Detection limit:*
The analytical sensitivity of Amedica Drug Screen MDMA-BAR-BZO-MTD-TCA Test were evaluated using the following 7 different

urine specimens with drug concentration ranging from negative to 3x cutoff. The specimens were prepared by spiking GC/MS confirmed drug standards into filtered drug free urine. The results of the sensitivity study are summarized as follows:

MDMA Conc. (ng/rnl)	No.of samples	-	+/-	+
	25	25	0	0
250	25	25	0	0
375	25	12	13	0
500	25	0	11	14
625	25	0	5	20
750	25	0	0	25
1500	25	0	0	25

BAR Conc. (ng/ml)	No. of samples	-	+/-	+
0	25	25	0	0
150	25	25	0	0
225	25	11	14	0
300	25	0	13	12
375	25	0	7	18
450	25	0	0	25
900	25	0	0	25

BZO Conc. (ng/ml)	No of samples	-	+/-	+
0	25	25	0	0
150	25	25	0	0
225	25	10	15	0
300	25	0	12	13
375	25	0	0	17
450	25	0	0	25
900	25	0	0	25

MTD Conc (rng/ml)	No of samples	-	+/-	+
0	25	25	0	0
150	25	25	0	0
225	25	11	14	0
300	25	0	11	14
375	25	0	8	17
450	25	0	0	25
900	25	0	0	25

TCA Conc (ng/ml)	No of samples	-	+/-	+
0	25	25	0	0
125	25	25	0	0
18.75	25	10	15	0
25	25	0	13	12
31.25	25	0	9	16
37.5	25	0	0	25
75	25	0	0	25

e. Analytical specificity:

The specificity of Amedica Drug Screen MDMA-BAR-BZO-MTD-TCA has been tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in filtered drug-free normal human urine.

The following structurally related compounds produce positive results when tested at levels greater than the concentrations listed below.

Compound	Concentration (ng/ml)
MDMA	
3,4 methylenedioxymethamphetamine (MDMA)	500
d-Methamphetamine	250
d-amphetamine	10,000
1-Methamphetamine	500
Methylenedioxyethylamphetamine (MDEA)	500
p-Methoxyamphetamine (PMA)	>100,000
34 methylenedioxyamphetamine (MDA)	>100,000
BAR	
Secobarbital	300
Alphenal	400
Amobarbital	2,000
Aprobarbital	300
Barbital	300
Butabarbital	300
Butalbital	3,000
Pentobarbital	400
Phenobarbital	300
BZO	
Oxazepam	300
Alprazolam	200
Bromazepoxide	1,500
Chlordiazepoxide	500
Clobazam	400
Clonazepam	50,000
Diazepam	300
Estazolam	500
Flunitrazepam	1,500
Flurazepam	1,000
Lorazepam	3,000
Lometazepam	10,000
Medazepam	50,000
Nitrazepam	20,000
Nordiazepam	400
Prazepam	5,000
Temazepam	3,000
Triazolam	50,000

MTD	
Methadone	300
(±)-2-Ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium	50,000
2-Ethyl-5-methyl-3,3-diphenylpyrroline (EMDP)	50,000

TCA	
Nortriptyline	1,000
Amitriptyline	1,000
Desipramine	800
Imipramine	1,000
Nordoxepline	1,500
Cyclobenzaprine	3,000
Clomipramine	10,000
Doxepine	1,500
Protriptyline	3,000
Perphenazine	50,000
Promazine	30,000
Trimipramine	5,000

The following compounds were found not to cross-react when tested at concentrations of 100 ug/ml.

Acetaminophen, Acetone, Albumin, Ampicillin, Aspartame, Atropine, Benzocaine, Bilirubin, Caffeine, Chloroqulne, Chlorpheniramine, Creatine, Dexbrompheniramine, Dextromethorphan, 4-Dimethylamincantipyrine, Dopamine, Doxylamine , (+/-)-Ephedrine, Erythromycin, Ethanol, Furosemide, Gualacol Glyceryl Ether, Glucose, Hemoglobin, Isoproterenol, N-Methyl-Ephedrine, (+)-Naproxen, Oxalic Acid, Penicillin-G, Pheniramine, Phenothiazine, L-Phenvleohrine, β-Phenylethylamine, Procaine, Quin CBHBHNNHG idine, Ranitidine, Sodium Chloride, Sulindac, Thioridazine, Tyramine, Vitamin C

There is a possibility that other substances and/or factors not listed above may interfere with the test and cause false results, e.g., biological, technical or procedural error. Amedica Drug Screen MDMA-BAR-BZO-MTD-TCA Test performance was evaluated using cutoff specimen and found no interferences when pH is between 4.5 to 8.5 and specific gravity is between 1.005 to 1.03.

f. Assay cut-off:

The identified cutoff except for MTD and TCA are recommended for use by Substance Abuse and Mental Health Services Administration (SAMHAS).

2. Comparison studies:
   a. *Method comparison with predicate device:*
   The Amedica Drug Screen MDMA-BAR-BZO-MTD-TCA Test accuracy has been evaluated using urine samples from clinical laboratories where they were analyzed by reference method, GC/MS. The test agreement with GC/MS results are as follows:

MDMA

New test	GC/MS Negative < -25%	GC/MS Negative -25% to cutoff	GC/MS Positive Cutoff to +25%	GC/MS Positive >+25%	% agreement with GC/MS
+	0	2	7	41	94.1
-	55	9	3	0	97.0

BAR

New test	GC/MS Negative < -25%	GC/MS Negative -25% to cutoff	GC/MS Positive Cutoff to +25%	GC/MS Positive >+25%	% agreement with GC/MS
+	0	2	12	42	96.4
-	45	13	2	0	96.7

BZO

New test	GC/MS Negative < -25%	GC/MS Negative -25% to cutoff	GC/MS Positive Cutoff to +25%	GC/MS Positive >+25%	% agreement with GC/MS
+	0	2	9	31	97..6
-	67	12	1	0	97..5

MTD

New test	GC/MS Negative < -25%	GC/MS Negative -25% to cutoff	GC/MS Positive Cutoff to +25%	GC/MS Positive >+25%	% agreement with GC/MS
+	0	3	8	44	96.3
-	51	13	2	0	95.2

TCA

New test	GC/MS Negative < -25%	GC/MS Negative -25% to cutoff	GC/MS Positive Cutoff to +25%	GC/MS Positive >+25%	% agreement with GC/MS
+	0	2	8	47	94.8
-	50	8	3	O	96.6

   b. *Matrix comparison:*
   Not Applicable. The assay is intended for only one sample matrix.

3. Clinical studies:
   a. *Clinical sensitivity:* NA

b. Clinical specificity: NA

c. Other clinical supportive data (when a and b are not applicable): None

4. Clinical cut-off: NA

5. Expected values/Reference range: NA

M. Conclusion:

Based on the information provided, I recommend that the Amedica Drug Screen MDMA-BAR-BZO-MTD-TCA Test is substantially equivalent to the legally marketed predicate device.